



MEMORANDUM

TO: Marijuana Control Board DATE: April 6, 2022

FROM: Jane P. Sawyer, Regulations Specialist RE: Regulations Project – Dairy
butter, oils, or fats as sold as
stand-alone edible product

At the last meeting, the board discussed allowing marijuana infused dairy butter, oils, and fats to be prepared as stand-alone edible products for sale (to the consumer through a retail), but the current regulation 3 AAC 306.555(b)(2) does not allow for this.

The problem that we ran into in attempting to amend the regulation to allow for the stand-alone product for sale, was answering questions such as: is a food-based dairy butter, oil, or fat, a marijuana concentrate? Or a marijuana product? Can it be made by a concentrates-only facility or can it only be made by the full product manufacturing facility?

For example, 306.555(b) says: “*a marijuana product manufacturing facility may create marijuana concentrates only as follows: ...*” does this mean that only product manufacturing facilities can make concentrates because it does not specify: “*including marijuana concentrate manufacturing facilities*” like in other sections of 306.500? We do not think so, but this inconsistency exists throughout 306.500.

Further, 3 AAC 306.555 lists the methods that may be used to create or make or produce a concentrate. But .555(b)(2) sort of throws the provision for a spin when it states “*food-based marijuana concentrate may be produced by extracting cannabinoids from marijuana through the use of propylene glycol, glycerin, butter, olive oil, or other typica cooking fats; **infused dairy butter, oils, or fats derived from natural sources may be used to prepare infused edible products; infused dairy butter, oils, or fats may not be prepared as stand-alone edible product for sale;***” it is, at least, confusing: are we talking about methods to create or make or produce concentrates or are we talking about what a concentrate is. Or are we just not understanding this.

Under statute AS 17.38.900(15), “marijuana product” means concentrated marijuana products and marijuana products that are comprised of marijuana and other ingredients and are intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures—the statute does not have a separate definition for “marijuana concentrates”.

Under regulations,

3 AAC 306.990(b) “concentrate” or “marijuana concentrate” means resin, oil, wax, or any other substance produced by extracting or isolating cannabinoids, THC, or other components from a marijuana plant or from materials harvested from a marijuana plant.

3 AAC 306.990(b)(17) “extraction” or “marijuana extraction” means production of marijuana concentrate by any water-based, food-based, or solvent-based method.

The board has been approving infused edible butters as “concentrate” products to be used as an ingredient in other edible products (whether these products can be made under the current regulations by concentrates-only facilities, it’s one of the questions) but at the last meeting, the board approved a “Flavored Butter” as a marijuana product that can be prepared and sold as a stand-alone marijuana infused edible product—this product is made by a full product manufacturing facility.

The amendments to the regulations to allow for stand-alone infused butters, oils, fats will depend on the results of the conversation and whether the board wants to pursue the project.

(Words in boldface and underlined indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted.)

3 AAC 306.505. Marijuana product manufacturing facility privileges

(a) Except as provided in 3 AAC 306.515, a licensed marijuana product manufacturing facility, including a marijuana concentrate manufacturing facility, is authorized to

(1) purchase marijuana from a marijuana cultivation facility or from another marijuana product manufacturing facility;

(2) extract marijuana concentrate in compliance with 3 AAC 306.555;

(3) manufacture, refine, process, cook, package, label, and store marijuana products approved under 3 AAC 306.525, including

(A) marijuana concentrate; or

(B) any product intended for consumption or use on the body that is comprised of marijuana and other ingredients, including edible products, ointments, salves, patches, or tinctures;

(4) sell, distribute, or deliver marijuana extract or any marijuana product only to a licensed retail marijuana store or to another licensed marijuana product manufacturing facility;

(5) provide and transport samples of marijuana concentrate or other marijuana product to a licensed marijuana testing facility for testing;

(6) provide a sample of marijuana concentrate or a marijuana product approved under 3 AAC 306.525 to a licensed retail marijuana store for the purpose of negotiating a sale;

(7) store inventory in a restricted access area on the licensed premises as provided in 3 AAC 306.535;

(8) transport marijuana in compliance with 3 AAC 306.750;

(9) conduct in-house testing for the marijuana product manufacturing facility's own use.

(b) A licensee of a marijuana product manufacturing facility, including a licensee of a marijuana concentrate manufacturing facility, may also apply for a marijuana cultivation facility license, retail marijuana store license, or both. A licensee of a marijuana product manufacturing

facility, including a licensee of a marijuana concentrate manufacturing facility, who obtains a marijuana cultivation facility license, retail marijuana store license, or both shall

(1) conduct any marijuana cultivation operation in a room separate from any other operation and the marijuana product manufacturing facility, and shall conduct any retail marijuana store operation in a room separate from any other operation and the marijuana product manufacturing facility; if the rooms are connected and co-located, a secure door must separate the rooms from each other; a secure door must separate any room connected to and co-located with the marijuana product manufacturing facility; and

(2) comply with each provision of this chapter that applies to any other type of marijuana establishment license that the licensee of a marijuana product manufacturing facility or marijuana concentrate manufacturing facility obtains. (Eff. 2/21/2016, Register 217; am 12/10/2020, Register 236)

3 AAC 306.525. Approval of concentrates and marijuana products

(a) A marijuana product manufacturing facility, including a marijuana concentrate manufacturing facility, must obtain the board's approval for each product it will manufacture for sale or transfer to another licensed marijuana establishment **or that it will use as an in-house ingredient.** The board will not approve a product that is prohibited under 3 AAC 306.510(a)(4).

(b) An applicant for a marijuana product manufacturing facility license request the board's approval of its intended products with a new license application by including, in its operating plan

(1) a photograph, drawing, or graphic representation of the expected appearance of each final product; and

(2) the proposed standard production procedure and detailed manufacturing process for each product.

Commented [SJP(1): This is not a new thing (it's just not currently in reg), the board has been requiring licensees to get approval of marijuana infused products that are used as ingredients for other products even if they are in-house products.

(c) A licensed marijuana product manufacturing facility may at any time submit a new product approval request to the board on a form the board prescribes along with the fee required under 3 AAC 306.100(c).

(d) A licensed marijuana product manufacturing facility shall keep its ingredient list and potency limits for any food product containing marijuana on file at the marijuana product manufacturing facility's licensed premises. The ingredient list and potency limits for any product manufactured at the facility must be made available for inspection on request by the director, or an employee or agent of the board. (Eff. 2/21/2016, Register 217)

3 AAC 306.555. Production of marijuana concentrate

(a) Before producing marijuana concentrate for sale, a marijuana product manufacturing facility shall develop standard operating procedures, good manufacturing practices, a safety plan, and a training plan for each individual employed in an extraction process.

(b) A marijuana product manufacturing facility may create marijuana concentrates only as follows:

(1) water-based marijuana concentrate may be produced by extracting cannabinoids from marijuana by using only water, ice, or dry ice;

(2) food-based marijuana concentrate may be produced by extracting cannabinoids from marijuana through the use of propylene glycol, glycerin, butter, olive oil, or other typical cooking fats; infused dairy butter, oils, or fats derived from natural sources may be used to prepare infused edible products **or prepared by a marijuana product manufacturing facility as a stand-alone edible product for sale provided that the potency limits set out in 3 AAC 306.560 and packaging requirements in 3 AAC 306.565 are observed for each marijuana product offered for sale by a retail marijuana store;** [INFUSED DAIRY BUTTER, OILS, OR FATS MAY NOT BE PREPARED AS STAND-ALONE EDIBLE PRODUCTS FOR SALE;]

(3) solvent-based marijuana concentrate may be produced using the hydrocarbons N-butane, isobutane, propane, or heptane or other solvents or gases the board approves that

Commented [SJP(2): This is very complicated. The reading of .555(b)(2) is not well understood or is interpreted in different ways. What does 305.555(b)(2) mean?

is the board wanting to allow the manufacturing of the stand-alone product by both manufacturing facilities without restrictions?

exhibit low to minimal potential human health- related toxicity; approved solvents must be of at least 99 percent purity and must be used

(A) in a professional grade closed-loop extraction system designed to recover the solvents;

(B) in an environment with proper ventilation; and

(C) with control of all sources of ignition if a flammable atmosphere is or may be present.

(c) A marijuana product manufacturing facility using a professional grade closed-loop gas extraction system shall ensure that

(1) each vessel is used in compliance with the manufacturer's stated pressure ratings;

(2) any carbon dioxide used is of at least 99 percent purity;

(3) a person using a solvent or gas to extract marijuana concentrate in the closed-loop system is fully trained on how to use the system, has direct access to applicable material safety data sheets, and handles and stores the solvent and gas safely;

(4) a licensed engineer has certified that the professional grade closed-loop system was commercially manufactured, is safe for its intended use, and is built to codes of recognized and generally accepted engineering practices; and

(5) any professional grade closed-loop system, and other equipment and facilities used in the extraction process are approved for their use by the local fire code official and meet any applicable fire, safety, and building code requirements.

(d) A marijuana product manufacturing facility may use heat, screens, presses, steam distillation, ice water, and other methods without employing solvents or gases to create

(1) kief;

(2) hashish;

(3) bubble hash;

(4) infused dairy butter, oils, or fats derived from natural sources; or

(5) other extracts.

(e) A marijuana product manufacturing facility may use food-grade glycerin, ethanol, and propylene glycol solvents to create extracts. All ethanol must be removed from the extract in a

manner to recapture the solvent and ensure that it is not vented into the atmosphere. (Eff. 2/21/2016, Register 217)

3 AAC 306.565. Packaging of marijuana products

(a) A marijuana product manufacturing facility shall observe the potency limits set out in 3 AAC 306.560 in packaging each product for resale by a retail marijuana store.

(b) A container or packaging for any edible marijuana product produced by a marijuana product manufacturing facility may not have any printed images, including cartoon characters, that specifically target individuals under 21 years of age. In addition, the packaging must

(1) protect the product from contamination and may not impart any toxic or damaging substance to the product; and

(2) if the marijuana product contains multiple servings, be designed so that the marijuana product itself has markings or demarcations clearly delineating each serving of the product; for liquid marijuana products with multiple servings, the packaging must indicate the number and size of individual servings.

(c) [EXCEPT AS PROHIBITED IN 3 AAC 306.555(b)(2),] A [A] licensed marijuana product manufacturing facility, **including a marijuana concentrate manufacturing facility,** may transfer marijuana concentrates in wholesale packages not to exceed 10 pounds to another licensed marijuana product manufacturing facility or a licensed retail marijuana store.

(d) Each packaged marijuana product must be identified by a tracking label generated by the marijuana product manufacturing facility's **or the marijuana concentrates manufacturing facility's** marijuana inventory tracking system.

(e) A licensed marijuana product manufacturing facility, **including a marijuana concentrate manufacturing facility,** shall prepare marijuana products for transfer to another marijuana establishment by

(1) placing marijuana products within a sealed, tamper-evident shipping container;

(2) affixing a label that complies with 3 AAC 306.570(d) to the shipping container; and

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(3) generating a transport manifest from the [MARIJUANA PRODUCT] manufacturing facility's marijuana inventory tracking system; the transport manifest must remain with the marijuana products at all times while being transported, and a copy must be given to the licensed marijuana establishment that receives the shipment. (Eff. 2/21/2016, Register 217; am 2/21/2019, Register 229; am 03/13/2020, Register 233)

For Discussion Only (it is not the entire Article 5)